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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,823	06/07/2001	Rolf Ehrhardt	05882.0003.P	2366

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,823	EHRHARDT ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 34-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 34-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 2/17/04, is acknowledged.
Claims canceled: 1-24, 26-33 and 43-44.
Claims amended: 25.
Claims pending: 25 and 34-42.

Claims 25 and 34-42 *are under consideration in the instant application.*

2. This Office Action will be in response to applicant's arguments, filed 2/17/04.
The rejections of record can be found in the previous Office Action.

3. Any objection or rejection not reiterated herein has been obviated by Applicant's amendment, filed 2/17/04.

Objections to the Claims

4. Claim 25 is objected to for the following informality: the claim recites a "method of treating a patient suffering from psoriasis consisting the step" when it appears the claim was intended to recite -- consisting of -- . Appropriate correction is required.

35 USC § 112 second paragraph

5. In view of Applicant's arguments and the evidentiary support that the term PASI was recognized in the art, the previous rejection of claim 42 under 35 U.S.C. 112, second paragraph, is withdrawn

35 U.S.C. § 102

6. Applicant's amendment, filed 2/17/04 and limiting the claims to a single method step (a method consisting of) has obviated the previous rejection of claims 25, 34-37 and 39-42 under 35 U.S.C. 102(a) as being anticipated by Strober et al. (WO 98/16248, IDS) because Strober et al. teach two method steps.

7. Applicant's amendment, filed 2/17/04 and limiting the claims to a single method step (a method consisting of) has obviated the previous rejection of claims 36-37 and 40-42 under 35 U.S.C. 102(b) as being anticipated by Strober et al. (WO 98/16248, IDS) because Strober et al. teach two method steps.

Claim Rejections – 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 25, 34-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (WO 96/40093, of record) in view of Leonard et al. (US Pat. No. 6,338,848, of record).

Applicant's amendment, filed 2/17/04, limits the claims to a single method step of administering a pharmaceutical formulation comprising an antibody that binds IL-12 and blocks IL-12 activity for the treatment of psoriasis.

Applicant's arguments in view of the amended claims, filed 2/17/04, have been fully considered but have not been found convincing for the reasons of record. Applicant's arguments are addressed below following a reiteration of the rejection of record as applied to the amended claims.

Gillies et al. teach methods of modulating immune reactions that lead to autoimmune disorders by inhibiting IL-12 (see entire document, e.g., Abstract). Gillies et al. teach methods of identifying compounds which inhibit IL-12 and in turn inhibit IFN-γ production (see entire document). Gillies et al. teach that compounds with this property are useful for treating the autoimmune disease multiple sclerosis and psoriasis (see page 25, first paragraph, in view of the background provided at pages 1-3).

Gillies et al. teach that small molecule inhibitors of IL-12 can be used in combination with other drugs to improve the effectiveness of the treatment (e.g., page 25, first paragraph).

Gillies et al. do not teach that antibodies can be used as antagonists of IL-12.

Leonard et al. teach methods of treating autoimmune diseases by administering antagonists of IL-12 to inhibit IFN-γ production (see entire document, e.g., Abstract). Leonard et al. teach IL-12 antagonists that are monoclonal antibodies that bind IL-12 and inhibit IL-12 activity (column 3 at line 64 to column 4 at line 37). Leonard et al. teach that the monoclonal antibodies to IL-12 can be chimeric (column 4 at lines 1-4) and formulated in pharmaceutical compositions (column 6 at lines 54-67). Leonard et al. teach that the antibodies may be administered via any of a number of routes, including by intravenous or subcutaneous injection (see column 7, especially lines 1-10). Leonard et al. also teach that administration at dosages of 0.05 mg/kg to about 25 mg/kg (see column 7, especially lines 31-34), and that the administration would continue until a meaningful patient benefit is observed by the treatment provider (column 7, lines 10-44).

Leonard et al. teach combining therapies for the treatment of autoimmune conditions (column 7 at lines 39-44).

In view of the teachings of Gillies et al. that psoriasis can be treated using compounds that antagonize IL-12, and the teachings of Leonard that monoclonal antibodies can be used as IL-12 antagonists to treat autoimmune diseases increased by IFN-γ, it would have been obvious to the ordinary artisan at the time the invention was made to treat psoriasis by administering a monoclonal antibody that binds IL-12 and blocks IL-12 activity to a patient with psoriasis. The ordinary artisan at the time the invention was made would have been motivated to combine the anti-IL-12 antibody antagonist of Leonard et al. with the compounds of Gillies et al. because both references teach combining therapies and Gillies et al. note that combining therapies is advantageous to provide a more effective treatment. The ordinary artisan at the time the invention was made would have had a reasonable expectation that the anti-IL-12 antibody antagonist of Leonard et al. could be combined with the antagonists of Gillies et al. to provide a more effective treatment for psoriasis because Gillies et al. teaches the application of IL-12 inhibitors to the treatment of psoriasis and Leonard et al. teach that the antibodies also function as IL-12 inhibitors. It is noted that although the instantly amended claims are limited to a single step of administering, more than one compound may be found in the pharmaceutical formulation comprising the antibody.

Further, the ordinary artisan would have been motivated to select a monoclonal antibody with an affinity of at least 10^8 M^{-1} in order to have an antibody of sufficient affinity to function as a blocking antibody. Further it would have been obvious to administer a dosage which would reduce PASI by at least 50% because Leonard et al. also teaches administering the inhibitor until a meaningful patient benefit is observed by the treatment provider

Applicant argues that there is no motivation to combine the references with a reasonable expectation of success because Gillies et al. is limited to topical treatments whereas Leonard et al. does not teach administering the anti-IL-12 antibody topically. However, Gillies et al. does not limit the routes of administration to topically, as argued by Applicant. Rather Gillies et al. clearly teach on page 8 that the preferred route of administration includes "parenteral". Parenteral administration includes any route other than administration via the intestinal tract. In addition, as noted supra, Leonard et al. clearly appreciate that the anti-IL-12 antibody can be administered by any of a number of routes.

Applicant also argues that there is no reasonable expectation of successfully combining bis-compounds and antibodies because they have different properties. However, as noted supra both Gillies et al. and Leonard et al. clearly contemplate combining therapies and Applicant has provided no reason that these two compounds could not be combined in a single formulation. Gillies et al. include PBS and other pharmaceutical carriers on page 8 that are also used to formulate the antibody of Leonard et al.

Therefore, the Examiner maintains that the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (WO 96/40093, of record) in view of Leonard et al. (US Pat. No. 6,338,848, of record) as applied to claims 25, 34-37 and 39-42 above, and further in view of Gately et al. (US Pat. No. 6,225,117, of record).

Applicant's arguments in view of the amended claims, filed 2/17/04, have been fully considered but have not been found convincing for the reasons of record.

Applicant's argument is that the teachings of Gately et al. do not cure the defects in the teachings of Gillies et al. and Leonard et al. Applicant's arguments regarding Gillies et al. and Leonard et al. have been addressed supra and have not been found convincing.

The rejection of record is therefore maintained for the reasons of record.

11. Applicant's amendment, filed 2/17/04, has obviated the previous rejection of claims 25, 35, 37 and 38 under 35 U.S.C. 103(a) as being unpatentable over Strober et al. (WO 98/16248, IDS) in view of Gately et al. (US Pat. No. 6,225,117, of record) by limiting the method to a single method step.

Double Patenting

12. Applicant's willingness to file a terminal disclaimers to obviate the provisional rejections of record in view of copending Application No. 10/108,191 are acknowledged. However, until such time as the terminal disclaimer is filed or the claims are amended in copending Application No. 10/108,191 to obviate the provisional obviousness-type double patenting rejections, the following rejections are maintained for the reasons of record:

13. Claims 25, 34-37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 39-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191 in view of Leonard et al. (US Pat. No. 6,338,848, of record) for the reasons of record.

This is a provisional obviousness-type double patenting rejection.

15. Claim 38 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191 in view of Gately et al. (US Pat. No. 6,225,117, of record) for the reasons of record.

This is a provisional obviousness-type double patenting rejection.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark whose telephone number is (571) 272-0848. The examiner can normally be reached on Monday from 7:30 to 4:00, and on Tuesdays and Thursdays from 10:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 15, 2004

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